NDA 19-510
NDA 20-249

Merck Research Laboratories
Attention: Michelle W. Kloss, Ph.D.
BLA-20
West Point, PA 19486-0004

25 APR 2001

Dear Dr. Kloss:

Please refer to your supplemental new drug applications dated August 9, 2000, received August 10, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
19-510	S-027	Pepcid™ (famotidine) Injection
20-249	S-010	Pepcid™ (famotidine) Injection Premixed

These supplemental new drug applications provide for the addition of text in a new "Geriatric Use" subsection under the PRECAUTION section of the package insert.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

We remind you of our telephone conference on October 26, 2000, in which you committed to revising the "Dosage Adjustment for Patients with Severe Renal Insufficiency" subsection under the DOSAGE AND ADMINISTRATION section to reflect the need for dosage adjustment in patients with both moderate (creatinine clearance less than 50ml/min) and severe renal impairment. These revisions were submitted on December 20, 2000, as Prior Approval Supplements (NDAs 19-462/S-031, 19-510/S-029, 19-527/S-025, 20-249/S-012, and 20-752/S-006).

The final printed labeling (FPL) must be identical to the submitted draft labeling, and include the

revisions of the Prior Approval Supplements (NDAs 19-462/S-031, 19-510/S-029, 19-527/S-025, 20-249/S-012, and 20-752/S-006), once approved. These revisions are terms of the approval of this application.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul E. Levine, Jr., R.Ph., Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research